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| EXAMINER | | | | |
| KOLKER, DANIEL E | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/691,079

Applicant(s)

MERCKEN ET AL.

Examiner

DANIEL KOLKER

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 7, 9 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-7, 9, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. The remarks and amendments filed 12 June 2008 have been entered. Claims 1, 6 – 7, 9, and 15 are pending and under examination.

Maintained Rejections

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6 – 7, 9, and 15 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

This rejection stands for the reasons previously made of record and explained in further detail below. As set forth previously, the specification as originally filed fails to disclose or describe step d) of claim 1, measuring the phosphorylation activity of the Src protein following contacting a cell with a candidate agent in the presence of APP. The specification as filed does provide support for an assay comprising the steps of a) providing a Src protein and b) determining if a compound inhibits the activity of the Src protein; see for example p. 5 lines 16 – 30. Separately, the specification discloses the results of an experiment wherein APP was added, via transfection of APP-encoding vectors, to cells expressing Src and wherein the amount of APP_{sec} (the α -secretase product of APP) was measured in the presence and absence of Src; see Example 2 spanning pp. 9 – 10 of the specification. However, the specification as originally filed does not provide support for screening methods comprising measuring the degree of Src phosphorylation activity in an assay where both APP and a candidate compound are present.

On pp. 3 – 4 of the remarks filed 12 June 2008, applicant argues that original claim 8 provides support for the limitations of claim 1, part d). Applicant's arguments have been fully considered but they are not persuasive. Original claim 8, in particular step c) is drawn to measurement of the activity of Src in response to a candidate compound. However neither

original claim 8, nor original claim 1, from which claim 8 depended, allowed for inclusion of APP in the assay as well. In fact, the specification as originally filed indicates that measuring the degree of tyrosine phosphorylation of APP, the specific form of Src phosphorylation activity recited in claim 15, should not be performed as "[t]he mechanism by which active Src elicits such a dramatic increase in A β secretion is not clear. However, it might depend on phosphorylation of some other proteins, different from APP, since tyrosine phosphorylation of APP by Abl-PP does not result in increased A β levels" [emphasis added]. While the specification as originally filed mentions that APP can be tyrosine-phosphorylated as recited in claim 15, not only does the specification fail to disclose screening assays wherein the degree of Src-dependent phosphorylation is measured, the specification in fact points the public away from such a step.

Applicant also argues that the specification provides support for the specific step of measuring tyrosine phosphorylation of APP by Src at p. 7 lines 19 – 20 of the specification as originally filed. The examiner has closely studied the cited section and has determined that this is a conclusory statement as to a possible activity of Src and not an indication of a step to be performed in a screening assay. Screening assays are discussed generally at p. 5, but not at p. 7 lines 19 – 20. The specification fails to disclose assays conducted in the presence of both Src and APP wherein Src phosphorylation in general as recited in claim 1, or tyrosine phosphorylation of APP in particular as recited in claim 15, are measured in the presence of a candidate compound. Therefore the rejection of record stands. Claims 6 – 7 and 9 are included in this rejection as they depend from rejected claim 1.

Specification

3. The amendment filed 12 June 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Applicant changed the sentence beginning at p. 6 line 11 from:

"b) determining if a compound inhibits the expression of Src protein."

to:

"b) determining if a compound inhibits the activity of Src by measuring the activity of said Src protein in response to said candidate compound."

The amendment changes the specification and introduces new matter, since the specification as originally filed only contemplated determining if expression of Src protein was changed in assays wherein step a) is "providing a sequence which regulates Src". By the amendment of the sentence at p. 6 line 11, the disclosure is changed from determining if expression is changed to determining if activity is changed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

4. No claim is allowed.

The new objection was necessitated by applicant's amendment to the specification.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

September 2, 2008